Research Advisory Panel of California
Office of the Attorney General
455 Golden Gate Avenue, Suite 11000
San Francisco, CA 94102-7004

Core Review Submission Checklist

PHARMACEUTICAL COMPANY MULTICENTER CLINICAL TRIAL PROTOCOLS

Research Advisory Panel of California

The Research Advisory Panel requires all multicenter clinical drug trial protocols involving Schedule II controlled substances, or substance abuse research clinical trials, to be submitted - by the pharmaceutical company conducting the study - to the Panel office for review and approval prior to the start-up of any sites in California. Below is a checklist of the items required for Panel review:

A. COVER LETTER

The cover letter should be in the form of a request letter, from the Pharma company sponsoring the multicenter clinical trial study, for Panel review of the protocol to be used in the study. It should include the title of the study, anticipated startup and completion time lines, the number of California sites planned, and estimated number of subjects to be enrolled at each site. It should also include the name and phone number of a contact person in the Pharma company qualified to answer any concerns the Panel may find during its review of the protocol. Finally it should state that the below listed attachments have been included:

B. PROTOCOL	☐ **Copy of Clinical Trial Protocol Attached (Required)**
C. CONSENT	☐ **Copy of Template Consent Attached (Required)**
D. STUDY DRUG INFO	☐ **Monograph or Investigators Brochure Attached (Required)**

Note: Approval for multicenter clinical trial protocols is granted to the pharmaceutical company conducting the study, not the individual sites participating in the study. Hence the review and approval process is initiated by and granted to the pharmaceutical company sponsoring the multicenter study, and, accordingly, **applications will not be accepted from individual MD's or sites participating in a multicenter study.**